



PATENT
ATTORNEY DOCKET: 4380US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application Of:)
Russell G. Higuchi)
Group Art Unit: 1743)
Application Number: 08/968,208)
Examiner: J. Snay)
Filed: November 12, 1997)
For: Instrument for Monitoring Nucleic)
Acid Amplification)

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, Applicant submits herewith patents, publications or other information (listed below and/or on the attached Substitute Form PTO-1449A) that may be material to the examination of this application, and in respect of which there may be a duty of disclosure as set forth in 37 C.F.R. § 1.56, for consideration and to be made of record herein by the U.S. Patent and Trademark Office in the above-captioned application.

Statement of Related Patents and Applications

This application is a division of parent application Serial No. 07/695,201, filed May 2, 1995, now U.S. Patent No. 5,994,056 and a sibling of application Serial No. 08/470,532, filed June 6, 1995, now U.S. Patent No. 6,171,785. The parent '056 patent and the sibling '785 patent have previously been brought to the attention of the Patent Office in an Information Disclosure Statement filed July 20, 1998. This application is also the parent of unpublished co-pending child application Serial No. 09/717,707, filed November 20, 2000. The unpublished child '707 application is not listed on the attached Substitute Form PTO-1449A; however, consideration of this application and its pending claims is earnestly solicited, as unpublished patent applications are contemplated as proper IDS material (see the exception in 37 CFR § 1.98(a)(2)(iii) and

MPEP §609). In accordance with 37 CFR §1.98(a)(2)(iii), a copy of this co-pending child application and its currently pending claims is attached hereto.

Legal Proceedings

Pursuant to MPEP §1006.06(c), Applicant previously brought to the attention of the Patent Office various legal proceedings relating to Japanese (Patent No. 3136129) and European (Patent No. 0 872 562 B) counterparts of the above-captioned application. Several citations listed on the attached Substitute Form PTO-1449A correspond to documents filed in these various legal proceedings. In addition to these legal proceedings, Applicant notes that the following additional legal proceedings relating to Japanese counterpart Patent No. 3136129 are now pending:

- (8) Invalidation Appeal No. 2003-35449 filed with the Japanese Patent Office by Bio-Rad on October 30, 2003 (pending); and
- (9) PE Corporation (NY) vs. Bio-Rad, Tokyo District Court No. H-15 (mo) 15045 (Protest Against Preliminary Injunction No. H14 (wa) 9503).

Cite No. 52 is an English language translation of the decision by the Japanese Patent Office dismissing for lack of merit Bio-Rad's appeal challenging the validity of Japanese counterpart Patent No. 3136129 (Invalidation Appeal No. 2002-35399).

Cite No. 53 is an English language translation of the appeal brief filed by Bio-Rad in a second action appealing the validity of Japanese counterpart Patent No. 3136129 (Invalidation Appeal No. 2003-35449). Cite No. 54 corresponds to Exhibit Ko No. 8 of Cite No. 53, which in turn corresponds to Eigen *et al.*, "Report on Evolution Research," Department of Biochemical Kinetics, Max Planck Institute für Biophysikalische Chemie ("Eigen Report"). Based upon the allegations of Cite No. 53, Applicant has listed an *alleged* publication of April 18-20, 1991 for Cite No. 54. However, Applicant's inclusion of a publication date for Cite No. 54 is not an admission that the document constitutes a printed publication, or, if it is a printed publication,

that its date of publication was prior to the effective filing date of the above-captioned application. Applicant expressly reserves the right to challenge the availability of Cite No. 54 to the public and/or its date of availability at a later time.

Cite Nos. 55-58 are English language translations of briefs submitted by the parties in PE Corporation (NY) vs. Bio-Rad, Tokyo District Court No. H-15 (mo) 15045 (Protest Against Preliminary Injunction No. H-14 (wa) 9503). As the Examiner may recall, Applicants previously submitted the Decision of the Tokyo District Court granting a preliminary injunction against Bio-Rad in PE Corp. (NY) vs. Bio-Rad, Tokyo District Court No. H-14 (wa) 9503 (Preliminary Injunction Action) and Bio-Rad in PE Corp. (NY) vs. Bio-Rad, Tokyo District Court No. H-14 (yo) 22065 (Main Suit) (Cite No. 50 of Information Disclosure Statement dated October 24, 2003). Applicant believes the Decision accurately summarizes the arguments made by the parties in these actions. However, Applicant would be happy to provide copies of the briefs should the Examiner wish to review them. Cite Nos. 55-58 stem from Bio-Rad's protest against the preliminary injunction.

Cite No. 59 corresponds to Exhibit No. 21 of Cite No. 58 and appears to be a report on an international workshop allegedly held from April 18-20, 1991 at the Max-Planck Institute für Biophysikalische Chemie. No publication date is provided for this reference as it is unknown when, or if, it was distributed. It is clear from page 2 of the Foreword, which is dated June 1991, that the report was prepared after the workshop and after the priority date of May 2, 1991 of the instant application.

Cite No. 60 is the instant assignee's response to the Oppositions and Intervention filed against European counterpart Patent No. 0 872 562 B.

Cite Nos. 61-62 and 65-66 are English language translations of various briefs submitted by the parties in Applera v. Bio-Rad, Düsseldorf Regional Court Case No. 4a O 44/03. Cite Nos. 63 and 64 correspond to Exhibits B11 and B11a, respectively, of Cite No. 62. Exhibit B11 (Cite No. 63) corresponds to pages i, 1, 2, 53-56 and 65 of the Eigen Report. These pages of the Eigen Report were previously brought to the attention of the Patent Office in an IDS filed July 20,

2001. It is noted that, based upon the unsworn and undated statement of Prof. Manfred Eigen (Exhibit B11a; Cite No. 64), Cite No. 62 alleges a publication date of April 18-20, 1991 for Cite No. 63. Accordingly, Applicant has listed an *alleged* publication date of April 18-20, 1991 for this document. Applicant notes, however, that its inclusion of a publication date for Cite No. 63 is not an admission that the document constitutes a printed publication, or, if it is a printed publication, that its date of publication was prior to the effective filing date of the above-captioned application. Applicant expressly reserves the right to challenge the availability of Cite No. 63 to the public and/or its date of availability at a later time.

Cite Nos. 67-69 are English language translations of briefs submitted by the parties in *Applera vs. MJ Research, Düsseldorf Regional Court Case No. 4a O 262/02*.

Cite No. 51 corresponds to U.S. Patent No. 5,552,580. The owner of this '580 patent, Beckman Coulter, Inc., has sued the present assignee on this patent in a suit that is unrelated to the above-captioned application (U.S. District Court for the Central District of California Case No. SA CV 02-624 AHS). In their claims construction brief (included herewith as Cite No. 70), the present assignee's attorneys erroneously characterized a device described in the '580 patent as a thermal cycler. A corrected was filed with the Court on February 17, 2004 (included herewith, along with its Notice of Filing, as Cite No. 71).

While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR § 1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention under specifically designated as such.

In accordance with 37 CFR § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR § 1.56(a) exists.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR § 1.98 and MPEP § 609 and consideration of the foregoing plus the prompt return of a copy of

the enclosed Form PTO-1449 with the Examiner's initials in the left column in accordance with MPEP 609 are respectfully requested.

In accordance with 37 C.F.R. § 1.97(b), this Information Disclosure Statement is being submitted prior to issuance of a first Office Action on the merits following the filing of an RCE. Therefore, it is respectfully submitted that no fee is required for consideration of this information. However, in the event any fee is deemed necessary, the Commissioner is authorized to charge the required fee to the undersigned's Deposit Account No. 01-2213 (Order No. 4380US).

Respectfully submitted,

Dated: March 24, 2004

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